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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/453,350	05/30/95	HELLIN	0004,000

HM21/0518

CHIRON CORPORATION
INTELLECTUAL PROPERTY R440
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EXAMINER

SAOUD, C

ART UNIT PAPER NUMBER

1646

36

DATE MAILED: 05/18/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5 March 1998

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 25-27, 43-57 is/are pending in the application.
Of the above, claim(s) 46-54 is/are withdrawn from consideration.
☐ Claim(s) is/are allowed.
☒ Claim(s) 25-27, 43-45, 55-57 is/are rejected.
☐ Claim(s) is/are objected to.
☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number)
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Art Unit: 1646

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

Transitional After Final Practice

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 05 March 1998 has been entered.

Response to Amendment

2. Claims 55-57 have been added as requested in the amendment of paper #34, filed 05 March 1998. Claims 25-27, 57 are pending in the instant application. Claims 46-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention (see paper #31, paragraph #3).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

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5. Applicant's arguments filed 05 March 1998 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 102

6. Claims 25-27 and 43-45 remain rejected and newly submitted claims 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Heldin et al. (Nature 319: 511-514, 1986) for the reasons of record in paper #31 as applied to claims 25-27 and 43-45.

Newly submitted claims 55-57 recite the limitation that the excipient be "suitable for topical administration". However, the pharmaceutically acceptable excipient of Heldin et al. (phosphate buffer at a pH of 7.4; see Figure 1 legend) would be considered to be suitable for topical administration, and therefore, meets the limitations of the claims.

7. The Declaration under 37 CFR 1.132 filed 05 March 1998 is insufficient to overcome the rejection of claims 25-27 and 43-45 based upon Heldin et al. as set forth in the last Office action because: the Declaration asserts that the ODGF of Heldin et al. would not be free of human viruses or other proteins of human origin. This statement is not supported with any evidence of record. The Declaration also states that the "methods of purifying proteins from human sources ... cannot result in a protein product free of contaminating human proteins" (see page 3, paragraph 5 of Declaration). This statement is again not supported with any evidence. The prior

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art of Heldin et al. demonstrate a single band on a silver-stained gel, which is indicative in the art of a homogenous preparation of protein (Figure 1, page 512). Furthermore, Heldin et al. specifically state that "one homogeneous component of M_r 31,000 was obtained in non-reducing conditions" (page 511, column 2, lines 3-5). The Declaration has identified no human virus which would copurify with a molecular weight of 31,000. In addition, Heldin et al. state that no other amino acid sequence was obtained from the purified PDGF AA preparation (see page 512). Therefore, the evidence of record clearly supports the conclusion that the protein preparations and compositions were free of other human proteins and free of any viruses because Heldin et al. teach a purification to homogeneity, absent evidence to the contrary.

Applicant argues that "conventional protein purification methods used to isolate PDGF from human cells would not result in a completely pure product" (see arguments at page 4). However, no evidence has been provided to support this conclusion. Heldin et al. teach a homogeneous composition and Applicant has provided no evidence to doubt this teaching. Applicant argues that the Declaration provides evidence to the contrary, however, the Declaration merely alleges that the composition of Heldin et al. would contain contaminating protein. There is no evidence of record to support this conclusion. Applicant argues (spanning pages 4 and 5) that the Declaration states "it is a virtual certainty that trace amounts of human proteins were present in the ODGF preparations that were not detected". This conclusion has been made without any evidence to support it. The prior art teaching of Heldin et al. clearly demonstrates a single band on a silver-stained gel which is recognized in the prior art as being indicative of a homogenous

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preparation as is the amino acid sequencing which did not detect any other proteins present. The Declaration alleges that "the cell line may well have contained pathogenic viruses ^{from} ~~from~~ the patient" and that there would be no guarantee of the elimination of human viruses (see page 5 of response). As stated above, Applicant has provided no evidence of any virus which would be expected to copurify at M_r 31,000, and no evidence has been provided to contradict Heldin et al.'s teaching of homogeneity. Therefore, the evidence of record clearly supports the rejection which is maintained above.

Conclusion

8. No claim is allowed.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

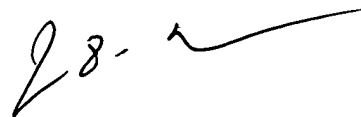
Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.

May 13, 1998

CS



JOHN ULM
PRIMARY EXAMINER
GROUP 1800